

Exhibit 23

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3
4 - - -
5

6 IN RE: BENICAR : MDL NO. 2606
7 (OLMESARTAN) PRODUCTS :
8 LIABILITY LITIGATION :
9 :
10 - - -

11 February 7, 2017
12 - - -

13 PROTECTED INFORMATION
14 - - -

15 Oral expert deposition of
16 STEPHEN M. LAGANA, M.D., taken pursuant
17 to notice, was held at the law offices of
18 Robins Kaplan LLP, 601 Lexington Avenue,
19 Suite 3400, New York, New York, beginning
20 at 10:09 a.m., on the above date, before
21 Kimberly A. Cahill, a Federally Approved
22 Registered Merit Reporter and Notary
23 Public.
24 - - -

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28

<p style="text-align: right;">Page 354</p> <p>1 A. Yep.</p> <p>2 Q. What does that mean, 4.82?</p> <p>3 A. It means that if we take the</p> <p>4 other ARB users to be the controls, if we</p> <p>5 said 1 out of -- these are made-up</p> <p>6 numbers and totally inaccurate, but if we</p> <p>7 said 1 out of a hundred patients taking</p> <p>8 an ARB other than olmesartan were</p> <p>9 hospitalized with a discharge diagnosis</p> <p>10 of celiac disease, 4.82 olmesartan users</p> <p>11 would be hospitalized with a discharge</p> <p>12 diagnosis of celiac disease.</p> <p>13 Q. A fourfold increase</p> <p>14 according to these data?</p> <p>15 A. Almost five.</p> <p>16 Q. Almost five.</p> <p>17 Doctor, in terms of the</p> <p>18 number of files examined, how does this</p> <p>19 study compare with the Mini-Sentinel?</p> <p>20 A. The number of patient years</p> <p>21 examined, you're asking?</p> <p>22 Q. Patient years or files out</p> <p>23 of which the analysis in the</p> <p>24 Mini-Sentinel was done -- let me back up.</p>	<p style="text-align: right;">Page 356</p> <p>1 MR. PARKER: Okay. Fair</p> <p>2 enough.</p> <p>3 BY MR. PARKER:</p> <p>4 Q. Doctor, I want to change</p> <p>5 subjects in the time I have left and move</p> <p>6 around a little bit.</p> <p>7 A. Sure.</p> <p>8 Q. Do you have an understanding</p> <p>9 of what is meant by the Bradford Hill</p> <p>10 criteria?</p> <p>11 A. I do.</p> <p>12 Q. Those criteria are not</p> <p>13 addressed, not mentioned, in your report;</p> <p>14 correct?</p> <p>15 A. Not specifically, no.</p> <p>16 Q. Have you ever published a</p> <p>17 paper of any type in which you used the</p> <p>18 Bradford Hill criteria to arrive at a</p> <p>19 conclusion of whether cause and effect</p> <p>20 relationship existed between a drug and</p> <p>21 an outcome?</p> <p>22 A. I think that the Bradford</p> <p>23 Hill criteria is something that we learn</p> <p>24 about in medicine and think about when</p>
<p style="text-align: right;">Page 355</p> <p>1 Do you know how the Mini-Sentinel was</p> <p>2 done?</p> <p>3 A. I wouldn't say I know</p> <p>4 exactly how it's done, no.</p> <p>5 Q. So you can't compare the</p> <p>6 size of the database that the FDA was</p> <p>7 looking at to arrive at their conclusions</p> <p>8 compared to what the French folks were</p> <p>9 looking at.</p> <p>10 A. I was not going to make that</p> <p>11 comparison, no.</p> <p>12 Q. Okay.</p> <p>13 Isn't the result obtained</p> <p>14 for celiac disease by the French people</p> <p>15 looking at their French data for</p> <p>16 olmesartan compared to other ARBs</p> <p>17 inconsistent with the FDA's analysis in</p> <p>18 the Mini-Sentinel on celiac disease?</p> <p>19 MR. SLATER: Objection;</p> <p>20 foundation.</p> <p>21 (Pause.)</p> <p>22 THE WITNESS: I don't see</p> <p>23 the Mini-Sentinel here. I don't</p> <p>24 know.</p>	<p style="text-align: right;">Page 357</p> <p>1 we're evaluating those questions, but</p> <p>2 I've never -- I've never, you know,</p> <p>3 specifically written a paper in which I</p> <p>4 looked at each point and made a response.</p> <p>5 Q. I take it from your last</p> <p>6 answer that in the period of time that</p> <p>7 you were writing your general causation</p> <p>8 report, you were aware of and understood</p> <p>9 the Bradford Hill factors criteria.</p> <p>10 A. I was familiar with the</p> <p>11 criteria.</p> <p>12 Q. And what is their use in</p> <p>13 medical science?</p> <p>14 A. They are a set of questions</p> <p>15 which are used to address cause and</p> <p>16 effect.</p> <p>17 Q. Can you explain for me why</p> <p>18 that methodology was not used in your</p> <p>19 report?</p> <p>20 A. I think it influences my</p> <p>21 thinking, those points influence my</p> <p>22 thinking. I didn't explicitly go through</p> <p>23 them because -- I don't know. Just did</p> <p>24 not do that.</p>

<p style="text-align: right;">Page 402</p> <p>1 causation, if that was the only thing 2 that changed. 3 Q. You were asked by counsel a 4 few minutes ago about a hypothetical 5 where he said a patient is assumed to 6 have taken olmesartan for two years and 7 then after two years develops diarrhea 8 that lasts for two days and, after those 9 two days are up, the person stops taking 10 olmesartan for whatever reason. 11 First question on that 12 person, would the differential diagnosis 13 -- if you were looking back 14 retrospectively to try to figure out what 15 had caused the diarrhea, would the 16 differential include olmesartan 17 enteropathy? Yes or no. 18 A. Yes. 19 Q. If you wanted to be more 20 sure of that at the time, when the person 21 stopped taking the drug and then got 22 better, would an endoscopy provide 23 information if the person had had an 24 endoscopy at that time?</p>	<p style="text-align: right;">Page 404</p> <p>1 diagnosis of malabsorption) are strong 2 arguments in favor of causality." 3 Is that statement of any 4 significance to you? 5 A. Well, yeah, I think it's a 6 -- it's a strong statement. They're 7 applying the Bradford Hill criteria 8 there, or at least some of them, and I 9 think that -- well, they've said it quite 10 plainly, that their findings are strong 11 evidence in favor of causality, and I 12 agree with that. 13 Q. You mentioned -- 14 A. And by the way, if I could 15 just mention another thing about this 16 study -- 17 Q. Sure. 18 A. -- which I don't think that 19 we got to too specifically, when you look 20 at the strength of the association, the 21 relative risk of 5 or 10 as is seen after 22 two years of therapy on olmesartan, 23 that's a very high relative risk. 24 Q. And why is that significant?</p>
<p style="text-align: right;">Page 403</p> <p>1 A. It certainly could, yeah. 2 Q. Could potentially. 3 A. Uh-hum. 4 Q. Would a rechallenge 5 potentially provide important information 6 as well if someone wanted to be sure -- 7 you know, you got better after two days. 8 Would giving the drug to the person again 9 and seeing whether it recurs, would that 10 be helpful information? 11 A. It would. 12 Q. And depending on the 13 findings, that would be clinical 14 information that would be factored into 15 an ultimate diagnosis? 16 A. It would. 17 Q. Now, looking at the Basson 18 article -- I'm just going to turn to it 19 real quick -- and looking at page 5 of 20 the article, and there's a statement here 21 on the top left, "The strength of the 22 association and the consistency with 23 reported cases (including the long lag 24 time between initiation of olmesartan and</p>	<p style="text-align: right;">Page 405</p> <p>1 A. Well, again, getting back to 2 the -- if we think about the Bradford 3 Hill criteria, the strength of the 4 association, the fact that there's a 5 tenfold increased risk is strong. 6 Q. And, you know, you've 7 mentioned the Bradford Hill criteria. 8 Counsel had asked you if it was 9 specifically mentioned in your report. 10 You didn't actually name that criteria; 11 correct? 12 A. That's true. 13 Q. Were you fully familiar with 14 that criteria when you did your report? 15 A. Yeah -- 16 MR. PARKER: Objection. 17 MR. SLATER: Let me ask the 18 question again. 19 BY MR. SLATER: 20 Q. Were you familiar with the 21 Bradford Hill criteria when you did your 22 analysis and wrote your report in this 23 case? 24 A. Yeah.</p>

<p style="text-align: right;">Page 406</p> <p>1 Q. Okay.</p> <p>2 Even though it was not</p> <p>3 named, did you take into account the</p> <p>4 factors in the Bradford Hill criteria in</p> <p>5 doing your analysis of the available</p> <p>6 information that you relied on in forming</p> <p>7 your opinion?</p> <p>8 MR. PARKER: Objection.</p> <p>9 MR. SLATER: You can answer.</p> <p>10 THE WITNESS: Okay. I think</p> <p>11 that those factors are fundamental</p> <p>12 to how people in medicine think</p> <p>13 about medical science, and</p> <p>14 certainly I did think about them</p> <p>15 and I did address them, although</p> <p>16 not in the context of listing the</p> <p>17 criteria point -- on a</p> <p>18 point-by-point basis. But, yeah,</p> <p>19 I did think about them and I did</p> <p>20 try to incorporate them.</p> <p>21 MR. SLATER: And I'm just,</p> <p>22 for the record, going to give you</p> <p>23 a list of the Bradford Hill</p> <p>24 criteria.</p>	<p style="text-align: right;">Page 408</p> <p>1 putting that all together, did you</p> <p>2 incorporate analysis of those factors</p> <p>3 that was implicit into your analysis of</p> <p>4 this material?</p> <p>5 MR. PARKER: Objection.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Coming back to the Basson</p> <p>9 article, towards the end at the bottom of</p> <p>10 page 5, there's a statement that says,</p> <p>11 "Patients treated with olmesartan should</p> <p>12 be informed about the risk of this</p> <p>13 complication, and should be advised to</p> <p>14 seek medical attention if they experience</p> <p>15 gastrointestinal symptoms. This</p> <p>16 information should also be widely</p> <p>17 delivered to physicians of all</p> <p>18 disciplines, particularly to</p> <p>19 gastroenterologists who are faced to this</p> <p>20 new category of patients."</p> <p>21 In the context of a question</p> <p>22 of whether there's -- whether the authors</p> <p>23 in this article had a viewpoint on</p> <p>24 causation, is that statement I just read</p>
<p style="text-align: right;">Page 407</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Strength of association,</p> <p>3 consistency, specificity, temporality,</p> <p>4 biologic gradient, plausibility,</p> <p>5 coherence, experimental evidence, and</p> <p>6 analogy, is that one way to describe</p> <p>7 those criteria?</p> <p>8 MR. PARKER: Objection.</p> <p>9 THE WITNESS: Yes, I believe</p> <p>10 so.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And I'll actually -- counsel</p> <p>13 objected, so I'm going to read you -- I'm</p> <p>14 going to ask you a different question.</p> <p>15 With regard to the Bradford</p> <p>16 Hill criteria, I'm going to list what I</p> <p>17 believe to be some of those factors and</p> <p>18 -- well, actually, you know what? I</p> <p>19 don't need to go through it again.</p> <p>20 Are you familiar with the</p> <p>21 Bradford Hill criteria factors?</p> <p>22 A. Yes.</p> <p>23 Q. In analyzing, for example,</p> <p>24 the literature and your experience and</p>	<p style="text-align: right;">Page 409</p> <p>1 to you of any significance?</p> <p>2 MR. PARKER: Objection.</p> <p>3 MR. SLATER: You can answer.</p> <p>4 THE WITNESS: Okay. I don't</p> <p>5 think there's really any vagary to</p> <p>6 that statement. I think that</p> <p>7 they're expressly stating that</p> <p>8 this is a new category of patient</p> <p>9 that we're now aware of. I think</p> <p>10 that they're saying this</p> <p>11 information is important, to be</p> <p>12 widely distributed. And I</p> <p>13 absolutely agree.</p> <p>14 The patients that we've seen</p> <p>15 at Columbia who suffered from this</p> <p>16 condition have been in terrible</p> <p>17 shape. Many have had</p> <p>18 life-threatening illness. And</p> <p>19 there's a million</p> <p>20 antihypertensives on the market.</p> <p>21 I -- you know, very rarely do you</p> <p>22 see this degree of improvement,</p> <p>23 both pathologically and</p> <p>24 clinically, with a fairly simple</p>